

### REMARKS

This is in response to the Office Action mailed August 2, 2002, and is accompanied by a request for a three-month extension of time.

At the outset, Applicant acknowledges with appreciation the indication of allowability of claims 47, 54 and 59.

The specification as well as claims 4, 17, 30, 47 and 54 have been amended to correct an error in chemical nomenclature. In particular, "(5,5-dimethylborinan-2-yl)" has been corrected to --5,5-dimethyl-[1,3,2]dioxaborinan-2-yl)-- throughout the specification and in those claims. No new matter is added, as it would be readily apparent from, e.g., the structure set forth on page 26 and elsewhere that the dioxaborinan compound was intended and in fact obtained.

In addition, claim 59 is amended to add additional indicator component monomers. Support is in, for example, original claim 54.

### 35 USC §102

Reconsideration and withdrawal of the rejection of claims 1-4, 10-12, 14-17, 23-25, 27-30, 36-38, 41-44, 48-51, 55 and 56 under 35 USC §102(e) as being anticipated by Van Antwerp '954 are respectfully requested.

The presently-rejected claims are directed to indicator macromolecules, their use to detect the presence or concentration

of analytes, and their preparation. In each instance, the claimed indicator macromolecule is a copolymer of a) one or more indicator component monomers, which individually are not sufficiently water soluble to permit their use in an aqueous environment, and b) one or more hydrophilic monomers. Copolymerizing the indicator component monomers with the hydrophilic monomers results in a macromolecule which may be used to detect analytes in aqueous environments. Moreover, quite surprisingly, under certain circumstances the indicator macromolecule exhibits an excimer effect. That is, due to the interaction between closely-located species such as anthracene, the macromolecule emits an additional characteristic longer wavelength emission which, surprisingly, is not responsive to changes in analyte concentration, but is responsive to all other aspects of the analyzed system. Thus, the indicator macromolecules which exhibit this effect may serve as both an indicator and an internal reference.

In contrast, Van Antwerp '954 does not disclose or suggest any such copolymers. Van Antwerp '954 is directed to an implantable amplification system which includes an amplification component immobilized in a polymer matrix. The immobilization takes place "either by entrapment or by covalent attachment" (col. 3, lines 32-35). The Van Antwerp '954 patent uniformly describes the relationship between the amplification components

and the polymer matrix as two separate entities in which the former is entrapped within or covalently attached to the latter. See, e.g., col. 3, lines 32-35; col. 7, line 60 to col. 8, line 4; col. 10, lines 25-28; col. 11, lines 7-10; and col. 15, lines 11-15. Thus, Van Antwerp '954 lacks any disclosure or suggestion of copolymerizing one or more indicator component monomers with one or more hydrophilic monomers to form an indicator macromolecule, and for that reason cannot anticipate any of the rejected claims.

Further, Van Antwerp '954 is likewise defective with respect to the rejected claims which recite the excimer effect (claims 41-44, 48-51, and 55-56). The possibility of the theory of excimer formation is not even hinted at in Van Antwerp '954, and there is no disclosure or suggestion in that reference that any of its amplification systems did in fact exhibit such an effect. There is thus no basis for the Examiner's assumption (page 2, ¶1) with respect to any of the excimer claims.

Thus, Van Antwerp '954 cannot anticipate any of the rejected claims.

Reconsideration and withdrawal of the rejection of claims 1, 2, 6, 10, 11, 12, 14, 15, 19, 23-25, 27, 28, 32 and 36-38 under 35 USC §102(e), or alternatively under 35 USC §103(a), as unpatentable over Colvin '360 are respectfully requested.

Colvin '360 is directed to the detection of analytes using fluorescent lanthanide metal chelate complexes. Colvin '360 neither discloses nor suggests the presently claimed copolymers of indicator component monomers and hydrophilic monomers. To the contrary, the complexes of Colvin '360 were used as is in solution (e.g., Example 1 and Figures 4-13). While Colvin '360 does disclose that its indicators "can be dispersed in a polymer matrix" (col. 33, lines 32-35), that simply is not a disclosure or suggestion of the presently-claimed copolymerization scheme.

Further, the Action admits that Colvin '360 does not disclose that the indicator component is not sufficiently water soluble to permit use in an aqueous environment, but assumes that they cannot be used directly in water (page 4, ¶5). The Action fails to cite any basis for that assumption, and it is nothing but speculation. Compounding the error, the Action next assumes that because the lanthanide complexes can be used in aqueous environments, then they must have been chemically manipulated somehow. A rejection under §102 or §103 cannot be based on an assumption on top of another assumption, neither of which has any basis in the reference. Therefore, Colvin '360 neither discloses nor suggests the presently rejected claims.

35 USC §103

Reconsideration and withdrawal of the rejection of claims 7, 20 and 33 under 35 USC §103(a) as being unpatentable over Van Antwerp '954 are respectfully requested.

The defects in Van Antwerp '954 are discussed above in connection with the rejection under §102(e). For the same reasons, Van Antwerp '954 does not suggest the presently-rejected claims. Indeed, Van Antwerp '954 teaches away from the use of copolymerized monomers by its teachings that the indicator should be either covalently attached to or physically entrapped within the biocompatible polymer. Additionally, each of claims 7, 20 and 33 contains the limitation that the molar ratio of hydrophilic monomer to indicator component monomer is from about 2:1 to about 1000:1. Van Antwerp '954 cannot suggest that range, because it does not employ the claimed monomers at all. Moreover, the Action alleges that the "general conditions" are taught in the prior art (page 3, ¶4), yet that is not true. The Examiner is respectfully requested to specifically point out where Van Antwerp '954 teaches molar ratios of monomer components.

Reconsideration and withdrawal of the rejection of claims 7, 20 and 33 under 35 USC § 103(a) as being unpatentable over Colvin '360 are respectfully requested. For the same reasons as described above, this rejection is defective. Moreover, because

Colvin '360 does not teach or suggest any copolymerized monomers, it cannot render obvious the specific molar ratio range of the presently-rejected claims.

Reconsideration and withdrawal of the rejection of claims 3, 4, 16, 17, 29, 30, 41-44, 48-51, 53, 55, 56 and 58 under 35 USC §103(a) as being unpatentable over Colvin '360 and further in view of Van Antwerp '954 are respectfully requested.

The defects in each of the references has been described above. The combination of the two references cannot make out a *prima facie* case of obviousness, because neither one suggests the formation of a copolymer from indicator and hydrophilic monomers, and neither suggests the ability to obtain an excimer effect.

#### **Double Patenting**

Reconsideration and withdrawal of the provisional rejections under 35 USC §101 and for obviousness-type double patenting based on pending claims in application Serial No. 09/632,624 are respectfully requested. It is Applicant's intention to allow that application to become abandoned in favor of the present application, which will render the present rejections moot.

Reconsideration and withdrawal of the rejection of claims 1, 2, 6, 10, 11, 12, 14, 15, 19, 23-25, 27, 28, 32 and 36-38 for obviousness-type double patenting in view of claims 13-18 of

Colvin '360 are respectfully requested. The present rejection rests on incorrect legal and factual grounds.

First, the Action asserts that the claims are not patentably distinct because, although they are not identical, the Colvin '360 complex is embraced by the present claims. That is not the proper legal question. As stated by the CCPA in reversing a double patenting rejection:

[I]t is elementary that readability of a claim on the subject matter of another claim (domination) is neither determinative of the double patenting issue nor demonstrative that claims are directed to the same invention.

*In re Sarett*, 140 USPQ 474, 482 (CCPA 1964). See also *In re Kaplan*, 229 USPQ 678, 681 (Fed. Cir. 1986):

[O]ne patent dominates another if a claim of the first patent reads on a device built or process practiced according to the second patent disclosure. This commonplace situation is not, per se, double patenting as the board seemed to think.

The proper inquiry is whether the rejected claims would have been obvious over the relied-on *claims* of Colvin '360. The answer to that is no. Claims 13-18 of Colvin '360 recite methods for detecting the concentration of an unlabeled analyte in a sample, utilizing particular fluorescent lanthanide metal chelate complexes. There is nothing in those claims which teaches that the claimed complexes are not sufficiently water soluble to permit their use in an aqueous environment. Moreover, the claims do not suggest that the water solubility problem, if present,

could be solved by copolymerization with a hydrophilic monomer. Indeed, the claims do not suggest copolymerization of an indicator component monomer with a hydrophilic monomer for any reason.

The Action suggests that the Colvin '360 complex is not sufficiently water soluble (page 7, ¶12), but that is not based on anything found in any of the relied-on claims. In making the §102(e)/103 rejection based on Colvin '360, the Examiner relied on what one of ordinary skill would infer from the Colvin '360 specification (¶5, page 4). To the extent that reliance is repeated, it is improper:

We are not here concerned with what one skilled in the art would be aware from *reading* the claims but with *what inventions the claims define*. [Original emphasis].

*In re Sarett*, 140 USPQ 474, 481 (CCPA 1964).

For the foregoing reasons, claims 13-18 of Colvin '360 do not render obvious any of the rejected claims of the instant application. Therefore the rejection is untenable and should be withdrawn.

As the case is believed in condition for allowance, a favorable Action is respectfully requested.

Respectfully submitted,



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